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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/799,299	03/12/2004	Gerald Horn	114309-1017	7833

7590 08/26/2005
BELL, BOYD & LLOYD LLC
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Chicago, IL 60690-1135

EXAMINER

HAND, MELANIE JO

ART UNIT	PAPER NUMBER
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3761

DATE MAILED: 08/26/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/799,299

Applicant(s)

HORN, GERALD

Examiner

Melanie J. Hand

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 19-22 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 19-22 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. ____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date 6/29/04, 8/24/04.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: ____.

DETAILED ACTION***Priority***

An application in which the benefits of an earlier application are desired must contain a specific reference to the prior application(s) in the first sentence(s) of the specification or in an application data sheet by identifying the prior application by application number (37 CFR 1.78(a)(2) and (a)(5)). If the prior application is a non-provisional application, the specific reference must also include the relationship (i.e., continuation, divisional, or continuation-in-part) between the applications except when the reference is to a prior application of a CPA assigned the same application number.

Double Patenting

A rejection based on double patenting of the "same invention" type finds its support in the language of 35 U.S.C. 101 which states that "whoever invents or discovers any new and useful process ... may obtain a patent therefor ..." (Emphasis added). Thus, the term "same invention," in this context, means an invention drawn to identical subject matter. See *Miller v. Eagle Mfg. Co.*, 151 U.S. 186 (1894); *In re Ockert*, 245 F.2d 467, 114 USPQ 330 (CCPA 1957); and *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970).

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double

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patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 19, 20, 21, and 22 provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 37 and 40, 39, 37, and 40, respectively, of copending Application No. 09/854,414 (U.S. Publication 2002/0082288 (IDS)). Although the conflicting claims are not identical, they are not patentably distinct from each other because they both claim imadozoline as the active agent and thus, the ophthalmic formulation is fully capable of contracting the pupil of a human patient's eye by 1.0 mm or more in dim light .

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claims 19 and 20 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1 and 12, and 11 and 13, respectively of U.S. Patent No. 6,291,498 (Horn)(IDS) in view of U.S. Patent No. 5,891,913 (Sallmann et al.) (IDS).

For claim 19, Horn teaches an ophthalmic formulation comprising an imidazoline that is capable of allowing the contracting of a pupil of a human patient's eye so that the pupil is reduced in diameter to a range of about 1mm to about 5mm. Horn, however, does not specifically claim a sterile aqueous carrier. It is well known in the ophthalmic

composition art that the active ingredient in the composition are dissolved in sterile aqueous carriers for delivery in the form of eye drops as shown in Sallman et al. (col. 4, lines 4-18) (applicant also admits this in section [0045]). Therefore, it is obvious to one with ordinary skill in the art at the time the ophthalmic composition was made to have a sterile aqueous carrier for delivery of the active ingredient (imidazoline) in the form of eye drops.

Claims 19 and 20 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 8 and 9, respectively, of U.S. Patent No. 6,420,407 (Horn) (IDS) in view of U.S. Patent No. 5,891,913 (Sallmann et al.)(IDS).

For claim 19, Horn teaches an ophthalmic formulation comprising an imidazoline that is fully capable of allowing the contracting of a pupil of a human patient's eye so that the pupil is reduced in diameter to a range of about 1mm to about 5mm. Horn, however, does not specifically claim a sterile aqueous carrier. It is well known in the ophthalmic composition art that the active ingredient in the composition are dissolved in sterile aqueous carriers for delivery in the form of eye drops as shown in Sallman et al. (col. 4, lines 4-18) (applicant also admits this in section [0045]). Therefore, it is obvious to one with ordinary skill in the art at the time the ophthalmic composition was made to have a sterile aqueous carrier for delivery of the active ingredient (imidazoline) in the form of eye drops.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Linh Truong whose telephone number is 571-272-4938. The examiner can normally be reached on Mondays-Fridays 10am-5pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Tanya Zalukaeva can be reached on 571-272-1115. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Linh Truong

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TATYANA ZALUKAEVA
PRIMARY EXAMINER

